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Tob Control 1999;8:225-235 (Summer)

Special report

The future of tobacco product regulation and labelling in Europe: implications for the forthcoming European Union directive

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► Summary

The European Commission has announced that it is considering legislation concerning further restrictions on cigarette tar and nicotine yields, as well as new provisions to regulate additives and the labelling of tobacco products. This report considers these issues and their relation to public health.

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In particular, we argue that further reductions in tar and nicotine yields as measured by the International Standards Organisation/Federal Trade Commission (ISO/FTC) method will be largely cosmetic and certainly misleading to consumers. If a new directive uses the ISO/FTC methodology as a basis for regulation, it risks lending further official support to the concept of "low tar" cigarettes, which may be used by smokers as an alternative to smoking cessation.

Although new regulations based on the ISO/FTC methodology may appear to offer health gains, these will be illusory and there may even be *negative health consequences*, as has been the case with these tests up to the present. We therefore make the following recommendations for the way forward.

ABANDON THE EXISTING APPROACH

It is widely recognised that the ISO/FTC test does not work—not least by the FTC itself. By legitimising the false claims of low tar cigarettes, it probably does more harm than good. It should be abandoned as a basis for measurement, regulation, and labelling of tobacco products in the new directive. The test should be kept only for archival continuity and replaced with other approaches (see

below) for measuring toxicity.

ESTABLISH A NEW BASIS FOR MEASUREMENT, REGULATION, AND LABELLING

This should include some or all of the following.

- Upper limits, and progressive reductions, for concentrations of known carcinogens and other toxins in smoke.
- A new measure of total toxicity.
- The ratio of specific carcinogens and other toxins to nicotine. This ratio could be reduced over time.
- Research should be commissioned to examine the pros and cons of setting an upper limit for nicotine yields. We currently advise great caution in the regulation of nicotine. Indeed there is a plausible argument in favour of *raising* the nicotine content of smoke. Smokers may respond to reduced nicotine content by increasing smoke intake to attain a satisfactory dose of nicotine. This would *increase* harm. The reverse may equally be true.

REGULATE TOBACCO PRODUCT ADDITIVES

The safety and wider public health impact of all additives need to be established in a way that takes into account the intended purpose, secondary purposes, or unintended effects of the additive—not simply the toxicity of the additive itself. Additives in use should be specified by brand. All existing and new additives should meet a test of public health or public interest or be withdrawn from use. In the case of additives that raise the bioavailability of nicotine, such as ammonia, there are plausible arguments for and against permitting these additives. At present, no evaluation of the overall public health impact is made. One possible model for regulatory supervision could be drawn from the pharmaceutical sector—NRT manufacturers wishing to add, say, mint flavour to nicotine gum have to undergo an arduous regulatory process.

REQUIRE FULL DISCLOSURE BY BRAND

There should be full disclosure of ingredients, additives, and smoke constituents by brand and this information should be made public. The Tobacco Sales Amendment Act in British Columbia provides a precedent for this. Nicotine content, the proportion of nicotine in "free" form in smoke and a puff-by-puff pH profile should also be given by brand. Concentrations of known carcinogens and other toxins in smoke and their ratio to nicotine should also be disclosed by brand as described above, and the tar/nicotine ratio should also be specified for reasons of historical comparison. The percentage ventilation of cigarette filters should also be given by brand.

REMOVE MISLEADING "LOW TAR" OR "LIGHTS" BRANDING

Consumer information on packets needs to be comprehensive and accurate. Specifically, branding such as "light" or "mild" or the use of colours or other techniques to imply health benefits which do not exist should not be permitted. Such implied claims and branding should be prohibited unless a genuine evidence-based health benefit, consistent with the implied health claim, can be established by the company to the satisfaction of an appropriate regulatory agency.

REMOVE MISLEADING TAR YIELD NUMBERS AND STRENGTHEN WARNINGS

FTC/ISO tar and nicotine yield ratings are thoroughly misleading and should be removed from the pack. A comprehensive list of warnings/messages should be included on packs or in package inserts.

MONITOR SOCIETAL NICOTINE DEPENDENCE

Exposure to nicotine needs to be regularly monitored by cross-sectional and cohort population surveys, including cotinine measurement.

DEVELOP REGULATORY CAPACITY

Plans should be set in place to establish a European Union (EU) tobacco product modification expert committee, and to develop a fully skilled, Europe-wide, nicotine regulatory body that would have the authority to regulate all nicotine containing products. A properly funded programme of research into product modification should also be commissioned.

DEVELOP A COMMON INTERNATIONAL STRATEGY ON THE FUTURE OF PRODUCT MODIFICATION

We recommend that efforts are made to establish a common international strategy on tobacco product modification, involving other international agencies such as the World Health Organisation. We envisage a three stage process.

1. Comprehensive disclosure of smoke constituents and additives, improved consumer information, and removal of misleading branding and labelling.
2. Regulation of toxic smoke constituents and additives—based on data disclosed in stage 1.
3. Regulation of all nicotine delivery products within a common framework. A common framework may not necessarily require identical standards, but given the radically different starting point of tobacco and other nicotine delivery systems, a new framework could establish common approaches to testing whether new product developments are in the public interest.

REVIEW AND UPDATE

Any future directive on these issues should be regularly reviewed and modified in the light of experience.

► **Background**

The European Commission has announced that it is considering legislation concerning cigarette tar and nicotine yields, additives, and labelling. Its proposal is expected to be based largely on the high level cancer experts committee of the "Europe Against Cancer" programme of the European Commission (referred to here as the cancer experts committee). In October 1996 this committee made a number of recommendations on tobacco, including further reductions in tar and nicotine levels, controls on additives, and changes in labelling.¹ We propose that, in the light of developments since these recommendations were written, some significant modifications are now appropriate.

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EU DIRECTIVES ON TAR AND RELATED LABELLING ISSUES

As tar has hitherto by general consent been agreed to be the major carcinogenic component of tobacco smoke, reductions in cigarette tar levels have been seen as a form of product modification with the aim of reducing harm. EU directives have therefore progressively reduced the permissible (machine-smoked) tar yield of cigarettes, the most recent (90/239/EEC) stipulating that by 31 December 1997, the tar yield of manufactured cigarettes was not to exceed 12 mg per cigarette. Directives on labelling (principally 89/622/EEC) have stated, *inter alia*, that tar/nicotine yields must be printed on the side of cigarette packs and should be measured on the basis of the ISO 4387 and ISO 3400 methods.

The cancer experts committee in October 1996¹ made the following recommendations concerning regulation of the content of cigarettes and labelling.¹

- "Only tobacco, tobacco paper, filter materials, and tobacco extracts should be permitted in cigarettes sold or manufactured in the EU. Any additives to be included should be demonstrated free of toxicity and other harmful effects on health, in burnt and unburnt form. Additives to cigarettes should be monitored and included on the labelling as with other drugs and foodstuffs on the market. The tar content of cigarettes should be limited to a maximum of 12 mg as currently mandated for 31 December 1997. The nicotine content of cigarettes should be limited to 1 mg from 31 December 1997."
- "The maximum allowable limits of the tar (12 mg) and nicotine (1 mg) contents of cigarettes sold or manufactured in the EU should be decreased by 10% per annum until levels of 5 mg tar and 0.5 mg nicotine are met."
- "By 31 December 1997, labelling requirements similar to those currently applicable in Australia should be in force. In particular, the health warning should be strengthened, made more prominent, and the labelling should include a toll-free telephone number from which accurate information about smoking, its health consequences, and smoking avoidance can be obtained. By 31 December 2000, generic packaging of cigarettes and tobacco products should be mandatory."

Given the role of the committee as formal advisers to the European Commission, it is possible that new legislation currently in preparation will be based on these recommendations.

In the next section we explain why we believe these recommendations should now be reconsidered and substantially modified. In particular, we believe the strategy of lowering machine measured tar yields is fundamentally flawed.

WHY LOW TAR CIGARETTES ARE MISLEADING CONSUMERS

It is widely and reasonably assumed that lower tar cigarettes deliver substantially less tar to the lungs and are therefore less dangerous. It is also widely (and quite rationally) assumed that the tar yields measured and printed on the box approximately represent tar exposure to the smoker and that a 5 mg tar cigarette will deliver approximately half the tar of a 10 mg cigarette. *Both assumptions are false, yet they continue to inform policy on tobacco product regulation.*

Tar and nicotine levels are measured by machines using a test based on the FTC approach that was adopted by the ISO. The machines use 35 ml puffs taken for durations of two seconds with one minute intervals between puffs, until the test cigarette has been shortened to a specified butt length. The tar and nicotine residues drawn into the machine are then measured.

However, this test does not measure what consumers ingest from their cigarettes, because people do not smoke like machines. Recent research indicates that, although smoking behaviour patterns vary between individuals, these patterns are skewed towards values that would result in higher deliveries of smoke than the values used in the standard machine-based test.² In other words, when the smoke is low in nicotine, people tend to take in more smoke than the machines.

The low tar rating of cigarettes results largely from the filter and the way this performs when tested in a smoking machine—rather than from any inherent change to the tobacco. The filter is designed to

retain more tar and nicotine than in higher tar cigarettes. It may also have ventilation holes at the side, to allow air to be drawn in to mix with the smoke, thereby giving a lower reading.

However, the addictiveness of nicotine means that smokers compensate for the reduced nicotine levels, and alter their smoking pattern to get their desired levels of nicotine. They can do this by inhaling more deeply, or by taking more frequent and larger puffs, or by blocking the ventilation holes in the filter.

Furthermore, modern cigarettes are designed to facilitate the discrepancy between people's smoking behaviour and the machine tests. One example is that the ventilation holes are never blocked by the machines but consumers can block them easily and even inadvertently.² The result is that when people smoke low tar brands, their actual tar exposure (and hence risks to health) may be almost the same as for conventional cigarettes. The FTC test is therefore perpetuating the fraud of low tar cigarettes. As BAT acknowledged privately in 1978³:

"[T]here is now sufficient evidence to challenge the advice to change to a lower delivery brand, at least in the short term. In general, a majority of habitual smokers compensate for changed delivery, if they change to a lower delivery brand than their usual brand. If they choose a lower delivery brand which has a higher tar to nicotine ratio than their usual brand (which is often the case with lower delivery products), the smokers will in fact increase the amounts of tar and gas phase they will take in, in order to take the same amount of nicotine. More realistic advice to smokers would be to choose a brand with a lower tar to nicotine ratio which gives them the satisfaction that they require in the lowest amount of smoke taken in."

This observation from within the tobacco industry makes two important points: first, that the FTC method does not work; second, that a better metric for health impact would be tar to nicotine (T/N) ratio. On these points, we agree with BAT, but with an important added qualification. The toxicity of the tar itself may change over time or from product to product and this will also affect the hazardousness of smoking. (It should also be noted that T/N ratio has reduced since the 1970s, not increased.)

The concept of "tar" is misleading. Tar is a collective name for thousands of chemicals that form the thick, sticky residue of tobacco smoke. It has markedly different compositions which are likely to cause different degrees of harm. Tar composition varies greatly between products. For example, cigarettes in Germany and in Japan have significantly lower levels of tobacco specific nitrosamines —important carcinogens—than cigarettes sold in the United States. There may also have been changes in tar composition over time in response to changing tobacco plant varieties and tobacco processing. The tar in potential product innovations such as Eclipse is of a very different nature; in Eclipse it is predominantly glycerol.

ARE LOW TAR CIGARETTES LESS HARMFUL?

There is uncertainty over whether the reductions in tar content of cigarettes over the past few decades have resulted in reductions in mortality and morbidity. A small reduction in risk of lung cancer has often been observed over time in the general population and among smokers of lower yielding brands, but whether this is caused by reduced yields is far from clear. Alternative explanations

include the following: self selection of lighter smokers with lower risk of smoking attributable disease to these brands; qualitative changes over time in the carcinogenicity of tar; and favourable changes in the tar to nicotine ratio of cigarettes, which mean that a given nicotine intake carries with it a lower tar exposure.

Furthermore, low tar cigarettes may have been mistakenly used as alternatives to quitting, so their introduction may have caused—and be continuing to cause—a higher number of smoking attributable deaths, than would have occurred had they not been an available option. In addition, recent studies have indicated that smoking low tar brands may be related to the increasing incidence of adenocarcinoma of the lung.⁴⁻⁶

The two largest, long duration studies of switching to low tar cigarettes, both of which randomised smokers and followed them over a period of six months, suggest that switching offers no significant health benefits as smokers compensate for reduced nicotine delivery.^{7,8} Both of these studies found it difficult to recruit and retain smokers for the study duration, illustrating smokers' resistance to shifting. One study observed complete nicotine compensation⁷ and in the other it was close to complete.⁸

In Canada, the British Columbia Ministry of Health⁹ has recently released detailed measurements of the major cigarette brands on sale in the province. Cigarettes were measured under different smoking conditions. For "light" cigarettes, the ministry concludes:

"Many smokers think that "light" cigarettes are safer than regular cigarettes, and that by smoking "light" cigarettes they will inhale fewer cancer-causing chemicals, or less nicotine. BC's new smoking tests have shown how wrong this belief can be. The reports filed by the tobacco companies show that light cigarettes are likely to deliver as many (or more) poisons and toxins to smokers as regular cigarettes." (See <http://www.cctc.ca/bcreports/light&mild.htm>)

FEDERAL TRADE COMMISSION VIEWS ON MACHINE MEASURED TAR AND NICOTINE YIELDS

In September 1997, the FTC solicited comments on proposed revisions to the FTC test. They acknowledged that changes in cigarette design and increased knowledge about human smoking behaviour had highlighted the limitations of the existing test method.

Their proposed revisions suggested that tar, nicotine, and carbon monoxide yields obtained under two different smoking conditions should be measured and that the resulting ranges should be disclosed in advertising. They also suggested that the system must be accompanied by public education to make smokers aware that individual exposure depends on how the cigarette is smoked, and that any benefits of switching to lower yield cigarettes are small compared with quitting. Finally, they recommended that the system should be re-examined at least every five years to evaluate whether the protocol is maintaining its utility to the smoker.

These proposals were strongly criticised by American scientists as not being sufficient to give consumers accurate information, or to give correct parameters for ensuring future reductions in harm.

The FTC has now withdrawn the proposed new methodology. In November 1998, the commission

wrote to the United States health secretary, Donna Shalala, acknowledging that the machine methods of testing tar, nicotine, and carbon monoxide yields are open to serious criticism and need a substantial rethink lasting 18 months. In this period, the FTC plans to launch adverts "designed to alert consumers to the significant limitations in existing tar and nicotine numbers". The proposed advertisements include such statements as: "Don't count on the numbers"; "Counting on low numbers? Get real"; "Think smoking a low tar and nicotine cigarette is "healthier"?—Give it up."

The message is clear—the FTC, which is the "owner" of these tests in the United States, no longer accepts them, and is prepared to advertise against them. The FTC also believes 18 months of further investigation is needed before it will be ready to propose an alternative.

The FTC machine measurements have been in use since 1967 and are used by tobacco companies to justify the marketing of "low tar", "lights", and "ultra" branding. The FTC's press release of 24 November 1998 acknowledges that it received critical comments in response to its initial proposals for a new methodology. The press release states: "The National Cancer Institute and US Food and Drug Administration stated in comments that new data suggests that the limited health benefits, previously believed to be associated with lower tar and nicotine cigarettes, may not exist."

PUBLIC UNDERSTANDING OF "LOW TAR" CIGARETTES

Research for the Health Education Authority¹⁰ in the United Kingdom assessed the attitude of smokers to low tar cigarettes. Over 1000 smokers were surveyed, just over a third (34%) of whom reported smoking cigarettes described as "light", "mild", or "ultralight" (collectively referred to from now on as smoking "light" cigarettes). Light cigarettes were more popular among women, smokers from non-manual social groups, and smokers aged 35 or over. Almost half (46%) of women smokers in non-manual social groups reported smoking light cigarettes.

A third of smokers who currently smoked light cigarettes said that a main reason for switching to a light brand was because they were worried about their health. Almost three out of 10 (28%) smokers also said that a main reason for switching was as a step towards quitting. Over a quarter (28%) of smokers thought that light cigarettes were less harmful than regular cigarettes. More than a third (36%) of smokers currently smoking light cigarettes thought them to be less harmful than regular brands.

HOW THE TOBACCO INDUSTRY COULD ACHIEVE A TAR REDUCTION OR NICOTINE LIMIT

If a new EU directive required cigarettes to have a maximum tar yield of 10 mg rather than the current 12 mg, this would be extremely easy for manufacturers to achieve. One way would be to make a small number of pin prick holes in the filters of cigarettes at the maximum of the permissible range. This would be sufficient to draw more air into the testing machine and reduce the measured tar yield. Smokers using these products would learn to block these holes or simply smoke more vigorously to achieve a "satisfactory" nicotine intake. Given that tar and nicotine in smoke come in a roughly fixed ratio of 10:1, manufacturers could use the same approach to limit nicotine.

Despite the appearance of action, there would be minimal or no health gain. At the same time, the directive would be lending unjustified credibility to the FTC/ISO measurement methodology, which in turn provides the justification for branding such as "low tar" and "light" for products that are below the maximum threshold established in the existing directive (90/239/EEC).

ADDITIVES TO TOBACCO PRODUCTS

Over 600 additives can be legally added to tobacco products in the European Union. Little is known about the potential harmful effects of many additives when they are burned with tobacco or in conjunction with other additives.

Crucially, the intended purpose of additives needs to be fully understood. If the purpose is to facilitate extra smoking or to increase the addictiveness of the product, it hardly matters whether the additive itself is toxic or benign. For example, the tobacco industry has acknowledged that the addition of alkali such as ammonia to increase smoke pH increases the availability of "free" or "unbound" nicotine and thereby increases the nicotine addictiveness for a given nicotine content. According to scientists from the tobacco companies:

"Since the unbound nicotine is very much more active physiologically, and much faster acting than bound nicotine, the smoke at high pH seems to be strong in nicotine."¹¹

"Methods which may be used to increase smoke pH and/or nicotine "kick" include: (1) increasing the amount of strong burley in the blend, (2) reduction in the casing sugar used on the burley and/or blend, (3) use of alkaline additives, usually ammonia compounds, to the blends, (4) addition of nicotine to the blend, (5) removal of acids from the blend, (6) special filter systems to remove acids from or add alkaline materials to the smoke, and (7) use of high air dilution filter systems. Methods 1-3 in combination represent the Philip Morris approach."¹²

"AT [ammonia technology] is the key to competing in smoke quality with PM [Philip Morris] worldwide. All US manufacturers . . . use some form of AT on some cigarette products."¹³

Thus some additives, although not directly toxic in themselves, may nevertheless increase tobacco-related harm by making cigarettes more palatable, attractive, or addictive to consumers. The example of ammonia highlights the problem in regulating additives merely according to the toxicity of the additive itself, rather than based on an assessment of whether the purpose of the additive, when used as intended, is in the public interest. Ammonia is one of many additives which could be challenged on public interest grounds. Others include additives that make smoke more palatable to the teenage palate, burn enhancers that keep cigarettes smouldering, and compounds that may dilate the bronchial passages.

CURRENT REGULATORY FRAMEWORK FOR TOBACCO ADDITIVES IS INADEQUATE

Ammonia technology is at least 25 years old, yet there have so far been no regulatory controls on its use. In the past quarter century, it is likely there have been numerous innovations in the field of tobacco additives—all with minimal regulatory scrutiny of the intended purpose of such additives.

The use of additives has been defended on the grounds that they may facilitate the acceptance of low yield cigarettes. As we argue above, such cigarettes are likely to offer minimal health benefits, and may blunt the motivation to quit. It is therefore difficult to justify the use of additives on this basis. Even if this was a genuine strategy, at the very least such additives should not be present in higher yielding cigarettes. This leads directly to the conclusion that regulators should know which additives

are in which brands and only permit them in brands where it could be proven that they would facilitate a public health gain.

The regulatory framework governing additives in the United Kingdom and the EU is flawed and should be substantially changed. In particular, we highlight the following problems.

- There are at least 600 *existing* additives licensed for use in the EU. There has been no systematic evaluation of the public health impacts of the effects of these additives when used as intended. It is quite possible that they add to the burden of harm caused by tobacco use, but regulators have no way of knowing or stopping them.
- Applications for new additives are subject to an unsatisfactory British voluntary agreement, in which no criteria are established for measuring the public health impact of the additive, or therefore for approval or rejection of applications on this basis. Although information must be supplied, there is no test of public health at the core of this agreement.
- Even the controls on additives in the British voluntary agreement can be easily circumvented by securing approval for the additive in a different EU member state. Once approved in an EU member state, the additive *has* to be permitted in all states. This will inevitably lead to tobacco companies seeking approval in the weakest regulatory regime.
- All additives should be covered by the regulations, including those to cigarette papers, filters and filter wrappers, and overwrappers.

REGULATION OF NICOTINE

There have been calls to reduce the nicotine content of tobacco products or smoke—for example, by the American Medical Association.¹⁴ The EU cancer experts committee advocated reducing machine measured nicotine yields to 0.5 mg.¹ It is also widely assumed that tobacco plants genetically engineered to have a high nicotine content, the so-called Y-1 strains, are a potential threat to public health. Furthermore, we demonstrated above a legitimate basis for concern about the addition of ammonia to cigarettes to raise the proportion of "free" nicotine in the tobacco smoke. This may have the potential to addict smokers more heavily and to make quit attempts more difficult.

However, an entirely different interpretation of these ideas is plausible. This is based on the "compensation" hypothesis underlying the critique of so-called low tar cigarettes above, namely that smokers adjust their smoking behaviour to achieve a satisfactory intake of nicotine. The following consequences could flow from this hypothesis.

- First, the reduction in the nicotine content of smoke (more precisely in the ratio of nicotine to toxins) may mean a higher intake of toxins if smokers inhale more smoke to achieve the nicotine dose they desire.
- Second, Y-1 high-nicotine tobacco leaves may allow a smoker to achieve the satisfactory dose of nicotine from less smoke, if this smoke, like the leaves, has a higher concentration of nicotine.
- Third, if smokers can achieve the same "satisfaction" with less nicotine because more of the nicotine in the smoke is in its free form, and therefore more bioavailable, it may be that ammonia *reduces* the smoke intake and harm.

There are good experimental data to demonstrate the validity of the first of these effects and the second follows logically from the first. The third is an open question—the addition of ammonia may

be harmful, but it could conceivably be beneficial. We are not aware of any published assessment of the public health implications of the addition of ammonia to cigarettes.

DISCLOSURE

An important prerequisite for developing more enlightened regulation must be a comprehensive disclosure regime. Regulators need a detailed characterisation of the product to specify regulations that would result in meaningful improvements. This detailed disclosure should be distinguished from the consumer information made available on packs (see below).

On 31 July 1998 the government of British Columbia became the first jurisdiction in the world to require tobacco companies to reveal the additives and ingredients in each brand of cigarettes, and to provide a detailed chemical analysis of the smoke of each brand of cigarettes.⁹ The Tobacco Sales Amendments Act requires companies to test their products for the presence of 41 toxic chemical constituents of smoke in addition to nicotine, tar, and carbon monoxide (these chemicals include formaldehyde and arsenic). In December 1997, the Liggett & Myers tobacco company in the United States became the first company to disclose the ingredients contained in its products.

The British Columbia data is extensively reported on a web site

<<http://www.cctc.ca/bcreports/default.htm>>. The information is therefore in the public domain. It is important to distinguish between the limited information made available on the pack, and requirements for more extensive disclosure. The appendix at the end of this article shows an example of the data supplied.

LABELLING ISSUES

Internal industry documents have clearly established that low tar cigarettes are being sold and marketed with the primary purpose of convincing the public that these products are safer. The branding of such cigarettes using terms such as "light", "mild", and "low tar" implies that they are safer. Other techniques, such as light colour or soft imagery can be used to add to the implied health claim.

For consumers to make informed decisions, the information they receive should be scientifically accurate, and comparable and consistent with the information made available for other products. Consumers should be able to assess risks with reasonable accuracy. Internal industry documentation indicates that the industry has known for at least 20 years that smoking machines were giving misleading readings, and senior tobacco industry scientists have admitted low tar cigarettes are a sham: "Irrespective of the ethics involved, we should develop alternative designs (that do not invite obvious criticism) which will allow the smoker to obtain significant enhanced deliveries should he so wish."¹⁵

PESTICIDE RESIDUES

A wide range of chemicals, including herbicides, fungicides, and insecticides are routinely used in tobacco growing to ensure maximum commercial production. There is evidence that pesticide residues in mainstream smoke may be retained by the smoker.¹⁶ It would be appropriate to set maximum limits on pesticide residues in tobacco products.

► Recommendations for discussion

1. The FTC test should be abandoned as the basis for the regulation of tobacco products

As we have argued extensively above, the FTC machine measured tar yield methodology gives profoundly misleading results as it ignores the nicotine compensating behaviour of human smokers. It has lent spurious legitimacy to the invalid health claims implicit in low tar/"lights" branding. It is no longer defended by the FTC itself, which is now seeking alternatives. We believe this methodology should be abandoned as the primary approach to measurement, regulation, and labelling of tobacco products in the European Union at the earliest opportunity. The FTC has launched an advertising campaign to warn of the dangers of taking the tar-yield numbers as any sort of index of harm. This is an important consumer awareness initiative and should be considered in other jurisdictions.

We recommend that the FTC test be kept only for archival continuity, and be replaced with other measures which will more accurately ascertain toxicity. Carbon monoxide measures should also be included in the tests. We suggest other potential measures below, but believe that further and full consideration is needed before a decision is made. This should take account of the 18 month review now underway in the United States.

2. Upper limits, and progressive reductions, for known carcinogens and other toxins should be set
Given the misleading nature of the concept of "tar" we suggest upper limits should be set for individual carcinogens and toxins in cigarette smoke. Specific emissions of toxins and carcinogens need to be measured in vapour and particulate phases.

Gray *et al*¹⁷ have recently suggested that existing brands could be tested for a selection of known carcinogenic substances, such as NNK (a tobacco-specific nitrosamine) and n-nitrosonornicotine. They also suggested that for substances with significant variability between brands, the median concentrations could be established as targets to which manufacturers would be given a time period to conform. This would ensure that achievable upper limits of such substances could be set. Brands unable to conform would be excluded from the country's market.

Progressive reductions for the known carcinogenic substances could then be established over time. Consideration needs to be given to which toxins are the most useful to monitor, and how to gauge dosing. However, we suggest that the measurement of these carcinogenic substances should be per unit of nicotine as discussed below.

3. A new measure of total toxicity should be introduced

One limitation with using only the above approach is that it allows the industry to reduce specified carcinogens, while possibly increasing other, unspecified carcinogens and other toxins in the process. A measure of total toxicity is therefore essential. The best method for this still needs to be ascertained but it could include, for example, a measure of total nitrogen content, or Ames tests.

4. The ratio of specific carcinogens to nicotine should be reduced

To prevent adverse effects of compensatory smoking which could erode the benefits of reduced carcinogenicity, we recommend that such reductions of toxins should be linked to nicotine. Although the health effects of nicotine have not yet been fully elucidated, they are clearly less than the health

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effects of many of the other aspects of cigarette smoke.

In the seventies it was suggested that cigarette smoking could be made less hazardous by reducing tar and other toxins relative to nicotine.¹⁸ Although this was never explicitly adopted as a public health strategy, the British government did recognise its potential advantages, in light of the compensatory nature of people's smoking. It therefore tolerated reductions in the average sales weighted tar/nicotine (T/N) ratio, which declined from 1972 to 1987. However, there is now a clear downward trend in nicotine yields in the United Kingdom (and indeed across the EU), in line with the enforced reduction in tar yields.

A policy to decrease the sales weighted T/N ratio assumes that a such a decrease, as measured by smoking machines, will be reflected in less tar being taken in by human smokers, per unit of nicotine absorbed. (See below for a discussion of how this would be measured). Rickert *et al*¹⁹ found that the T/N ratio could be increased by 50% or more by intense smoking.

It may be possible to specify a range of standard testing conditions for establishing the ratios. This approach has been adopted in British Columbia in which there is a standard test and a "realistic smoking" test.

Given the misleading nature of "tar", which is highly heterogeneous we recommend a reduction in specified toxic/carcinogenic substances in relation to nicotine yield. This would also include reductions in carbon monoxide/nicotine ratios. In effect, this is like viewing the tar components and toxic gases as "contaminants" in a nicotine delivery system. With nicotine as the denominator in the suggested ratios, there is an additional complexity arising from qualitatively different forms of nicotine ("free" or "bound"). The public health consequences of smoke with different compositions of free and bound form nicotine have not yet been established. In the light of further research, it may be possible to specify the nicotine content (the denominator of the ratio) in a way that more accurately reflects the drug "impact" of nicotine, taking account of its chemical form.

5. Regulation of nicotine should proceed with great caution and only after extra research

We urge caution and careful consideration of the possible unintended harmful consequences, before introducing regulations to limit or reduce the nicotine content of tobacco products.

Benowitz and Henningfield²⁰ have suggested limiting the maximum delivered dose of nicotine per cigarette, and base this on the nicotine content of tobacco and its bioavailability. They suggested a limit of 0.17 mg per cigarette, on the basis that this would be a threshold level for a less addictive cigarette which would be adequate to prevent or limit the development of addiction in most young people. Others,^{18 21} however, have suggested the limit be higher, recognising the problems that compensatory smoking may pose, as described above.

As mentioned earlier, a strategy which progressively reduces nicotine in cigarettes was again recently proposed by the American Medical Association.¹⁴ This approach pays little attention to scientific data on the factors driving smoker behaviour.²² It also poses serious risks of an expansion in the smuggling of higher nicotine cigarettes.

Because of the addictiveness of nicotine, we urge great caution in developing regulatory restrictions

on nicotine. Seemingly obvious "good ideas" like reducing nicotine content in cigarettes may have perverse consequences as smokers adjust their smoking to maintain blood nicotine levels. They may ingest more smoke to attain the nicotine they are seeking. Similar arguments apply to banning Y-1 high nicotine tobacco, and may plausibly apply to the enhanced bioavailability of nicotine created by the addition of ammonia.

Henningfield *et al*¹⁴ did acknowledge that research was needed in advance of a nicotine reduction strategy to, *inter alia*, examine the extent of compensatory smoking that occurs when reductions in nicotine are introduced. We recommend that no action is taken on nicotine yields before research is carried out into the pros and cons of setting nicotine limits. Researchers should remain open-minded about the plausible positive public health consequences that might arise from a strategy of reducing T/N ratios by *increasing* the nicotine content of smoke.

6. Tobacco additives should be tested for their wider public health impact

For additives, the cancer experts committee made the following recommendation¹: "Any additives to be included should be demonstrated free of toxicity and other harmful effects on health, in burnt and unburnt form. Additives to cigarettes should be monitored and included on the labelling as with other drugs and foodstuffs on the market."

We believe that the following modifications of the proposals by the cancer experts on additives need to be considered. In essence, *the purpose, use, and overall public health impact of existing and new additives need to be explained and justified.*

The toxicity of most additives would be swamped by the toxins present in tobacco smoke. What really matters is if the additive acts in such a way that it leads to increased smoking, thereby "leveraging" much greater harm than it causes directly. All additives should be covered by the regulations, including those to filters and papers.

Additives should be specified by cigarette brand. If, for example, an additive is present, as the companies might argue, to make a lower tar cigarette more palatable, then the additive should not be present in the higher tar brands. Knowledge of additives by brand will therefore be necessary to test some industry justifications.

The public health impacts of all additives (when used as intended, in conjunction with other ingredients, additives, etc) need to be appraised. The original justification for a liberal additives regime based on voluntary agreements, namely that additives would help smokers switch to lower tar brands, can no longer be sustained (as there is no meaningful public health benefit in the intended switch to low tar cigarettes).

In particular, we recommend the following.

- Burn enhancing additives should be banned.
- Those additives that increase pH or have any pharmacological effect need to be banned, at least until their overall safety can be convincingly established. These would include ammonia generators and other alkalinising agents. Other additives that may augment nicotine's effects through other means, such as levulinic acid, need also to be included here.

- Those additives that enhance palatability (often forming up to 4% of content) should be banned if when burnt they downgrade to pharmacologically active byproducts—as, for example, some sugars degrade to acetaldehyde. Additives that could plausibly aid initiation should be banned. Again, the criteria should be whether the additive offers a net public health benefit.

For each additive they wished to continue using, the tobacco companies should submit evidence that its overall effect (including its intended purposes) is not *adding* to the health consequences of tobacco or causing other damage. The burden of proof should be placed on the tobacco companies to make the case for continued use of each additive. The regulatory hurdles faced by a pharmaceutical company wishing to add flavourings to nicotine gum provide a starting point for development of a more robust regulatory framework for tobacco additives.

To add, say, mint flavour to nicotine gum, the manufacturer has to satisfy the pharmaceutical regulator that the additive does not:

- interfere with the efficacy or safety of the product
- increase the abuse potential of the product
- encourage a different pattern of use (indication) for the product.

It is clear that, in this sector, the regulatory machinery does exist to determine wider questions of public interest associated with the enhancement of products with additives. While questions regarding the safety, efficacy, and abuse potential of tobacco are inevitably non sequiturs, it may be possible to apply such criteria to tobacco additives by assessing the change of smoking behaviour they are intended to cause.

7. Introduce a comprehensive measurement and disclosure regime

There should be full disclosure of ingredients, additives and smoke constituents by brand. The British Columbia example is a good precedent for this and could be adopted as a basis for disclosure in the European Union.

Two important characteristics of cigarette smoke are its nicotine content and the proportion of that nicotine which is in "free" form. Free nicotine is volatile and more rapidly absorbed by the smoker. As the pH of smoke increases, a greater proportion of nicotine in smoke occurs in free form. Therefore, a reasonable proxy for free nicotine might be the pH of the smoke. It is possible that the cigarette design may be altered by the manufacturers to allow a higher pH for the first few puffs, to give an immediate nicotine "rush". The free nicotine content could be characterised by a puff by puff pH profile, which should also be given by brand. Tobacco industry documents released for the Minnesota trial show that the "free-basing" of nicotine using alkaline additives has been an important marketing strategy. This activity has so far escaped regulation.

Concentrations of known carcinogens and other toxins in smoke and their ratio to nicotine should also be disclosed by brand as described above. The tar/nicotine ratio could also be specified for reasons of historical comparison.

As discussed earlier, ventilation holes in cigarette filters have been used to lower machine tested tar yields. We also recommend that the ventilation percentage should be given by brand and that cigarettes are tested under a variety of smoking conditions, including with holes blocked and more

intensive smoking—more frequent and deeper puffs.

8. Consumer information on packets should be comprehensive and accurate

We make a number of recommendations concerning package labelling with respect to tobacco content only (this document is not concerned with health warnings/messages).

- Labelling such as "light" or "mild" should be prohibited. The implied claims are misleading and inaccurate. In any event, smokers should be warned that smoking so-called low tar cigarettes may not reduce their exposure to tar.
- Tar and nicotine ratings based on the existing FTC/ISO measurements should be removed from the pack. They are misleading and do not convey useful information.
- A comprehensive list of messages should also be included on packs or in package inserts. A suitable starting point for this list is contained in the Citizen's petition to the FDA.²³ Harris²⁴ drew up a suggested new label for cigarettes which could be used as a model. This includes yields of known carcinogens and other toxins. In support of this, research with smokers has indicated that almost a third wanted more information on harmful substances printed on the cigarette packet.¹⁰
- Where possible and appropriate, smoking cessation helpline numbers should be printed on the pack or included in a pack insert. This approach has been adopted in Australia.
- Australian packages also include a few sentences explaining the listed health message to help the consumer to understand the personal implications of the message.

9. Actual exposure of smokers to nicotine should be regularly monitored

Cross-sectional and cohort surveys of adults and children should be carried out throughout the EU to measure actual exposure to nicotine on a regular basis, including cotinine measurement. The surveys should include questions about use of the full range of nicotine delivering products currently available in each country, that is, cigarettes and other forms of tobacco, NRT, and any new products which may deliver nicotine more for recreational than therapeutic purposes. This is an important component of an evidence based approach to monitoring the effects of altered product design and would enable comparisons between countries taking different approaches to regulation.

10. Develop expert and regulatory capacity

It is clear that regulation of tobacco products is complex and requires expert advice and assessment of evidence. Less harmful forms of nicotine delivery than smoking do exist, such as nicotine replacement therapies. The tobacco industry has patented scores of alternative nicotine devices and some such products, for instance, Eclipse and Accord, are currently being test marketed in some countries. We believe that to reduce the harm associated with tobacco use, a common regulatory framework for all nicotine delivery systems should ultimately be developed. This could be enabled by an extension to pharmaceutical regulation to include all nicotine containing products, or by introducing new legislation to develop a new nicotine regulatory authority. Controls would be needed on all aspects of the product, similar to pharmaceutical regulation, including, purity, safety, and quality aspects as well as labelling, packaging, sales, and marketing. Initially, such a framework would prioritise adjustment of perverse regulatory imbalances that favour the dirtiest nicotine delivery over cleaner forms. A common framework may not necessarily require identical standards, but could establish common approaches to testing whether new product developments are in the public interest. Such a framework could eventually make it possible to minimise harm by

encouraging the production and marketing, for nicotine addicts, of less harmful forms of nicotine.²⁵

As part of this recommendation, we recognise that we need to build a knowledge and skill base of tobacco content, toxicology, etc. Funding should be provided for the development of toxicological, biochemical skills, etc. Funding needs also to be provided for a comprehensive programme of research into product modification. We also recommend that an EU tobacco product modification expert committee be set up, in addition to the EU cancer experts committee. Regulatory bodies should be given full authority to find out from the tobacco industry what they need to know to be able to carry out their roles properly.

11. A common international strategy on the future of product modification should be developed

We recommend that efforts are made to establish a common international strategy on tobacco product modification. As discussed above, the FTC test is under review in the United States, and tobacco product modification is also being examined in Canada. Other international agencies, such as the World Health Organisation, could help establish a common agenda. Such a strategy might start with comprehensive disclosure and improved consumer information and move to regulation based on the disclosed data.

Stage 1

- In principle decision to regulate tobacco products as nicotine drug delivery systems.
- Develop expert and regulatory capacity.
- Comprehensive measurement and disclosure of smoke ingredients under a variety of smoking conditions (along similar lines to the regime operating in British Columbia).
- Disclosure of additives by brand.
- Improved consumer information on or in the pack.
- Removal of misleading branding such as "light and mild".
- Removal of misleading tar and nicotine yields from packs.

Stage 2

- Progressive and tightening regulation of specific toxic smoke constituents in relation to nicotine levels.
- "Public interest" justification of new and existing additives and removal of additives if no satisfactory justification can be made.

Stage 3

- Regulation of nicotine market and novel nicotine delivery devices within a common framework to reduce overall levels of harm caused by tobacco products.
- Reduction of toxicity of nicotine delivery to low levels.

12. Any future directive on these issues should be regularly reviewed

Annual reviews of this directive need to be established to ensure that other recommendations can be incorporated in the light of new developments. There are many other ways cigarettes can be made less harmful; for example, taking steps to prevent blocking of ventilation holes, or making cigarettes fire safe. Action on Smoking and Health is currently examining tobacco industry patents to see if other

recommendations are feasible. We also recommend that the following be considered to see if there are any recommendations that could be made about them.

- Using activated charcoal or catalytic filters on cigarettes to reduce the levels of carbon monoxide and other vapour phase toxins.
- Mandating the process that eliminates nitrosamines from tobacco. Star Pharmaceuticals/Tobacco Technology (United States based) claim they have a relatively cheap technique for removing nitrosamines from tobacco. There are many patents suggesting technological options for reducing the harmfulness of cigarettes. If these are technologically possible, regulators should require that they are used.
- Considering whether there are any materials which should be required for inclusion in tobacco products that would lower their toxicity or addictiveness. (We believe the industry is looking at reducing the amount of tobacco and replacing with an inert filter.)
- Making cigarettes fire safe.

► Acknowledgments

This paper is based on discussions with David Sweanor, Luk Joossens, and Gillian Shine. It was also modified as a result of helpful comments from John Slade, Greg Connolly, Bill Rickert, and Michael Cummings.

► References

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Appendix: sample of data disclosed under British Columbia regime. Smoke constituents (in milligrams per cigarette) in Player's Regular reported to the British Columbia government in October 1998 in accordance with the Tobacco Sales Amendment Act

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